K012894 page 1 of 2

MAY - 7 2004

510(k) Summary
Linvatec Biomaterials
Osteo ACL Screw

Submitter's Name, Address, Telephone Number, and Contact Person

Linvatec Biomaterials Ltd.
Tuija Annala
Director, Quality and Regulatory Affairs
P.O.Box 3
FIN-33721 Tampere
Finland, Europe
Phone: 358-3-316 5600
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Date prepared: August 21, 2003

Name of the device:

A.	Trade or Proprietary Name:	Osteo ACL Screw
B.	Common Name:	Bioabsorbable Interference Screw
C.	Classification Name:	Bone Fixation Screw
D.	Device Product Code:	MAI and HWC

Predicate Device:

1. Linvatec Biomaterials Ltd (the previous Bionx Implants, Inc.) K993073
2. Mitek Products Mitek Biocryl Interference Screws (K012572)
3. Linvatec Inc BioScrew (K933719, K952831, K973758)
4. Biocomposites Ltd Biolok (K993630, K002070)

Intended Use:

The Osteo ACL Screw™ is intended for use in interference fixation of bone-patellar tendon – bone and soft tissue grafts in anterior and posterior cruciate ligament reconstructions.

The Osteo ACL Screw™ is not intended for use in and is contraindicated for 1) insufficient quality and quantity of bone for attachment of graft, 2) Blood supply limitation and/or previous infections, which could retard healing, 3) Foreign body sensitivity to the implant material. Where the material is suspected a test should be made prior to implantation to rule out sensitivity, 4) Patients with active sepsis or infection, 5) Conditions, which tend to limit the patient's ability or willingness to restrict activities or follow directions during the healing and rehabilitation period, 6) ACL repairs, which would not be appropriate for fixation with metallic screws.

Device Description:

The device description of the Osteo ACL Screw is as follows.

- The implant is composed of mixture of poly-96L/4D-lactide copolymer and tri-calsium phosphate. The predicate devices like Mitek Biocryl Interference Screws (013572) and Biocomposites Ltd Biolok (K993630, K002070) are utilizing mixture of poly-L-lactide and tri-calsium phosphate.
- Lengths of implant are 20 - 30 mm
- Diameters of implant are 7mm-11mm.

The only modifications that were made are:

- Amendment of a new raw material option, mixture of poly-96L/4D-lactide copolymer and tricalsiumphosphate (TCP).
- Design of driver hole is adapted of Linvatec BioScrew implant (K933719, K952831, K973758).
- Thread profile is adjusted to fit with bone taps of Linvatec BioScrew implant (K933719, K952831, K973758).
- Reference numbers for these new screw versions. These changes are updated in labelling.
- New trade name to separate it from SmartScrew ACL. This change is updated in labelling.
- Revision of insert sheet concerning adaption of instrumentation of BioScrew.

Substantial Equivalence:

Linvatec Biomaterials Ltd (the previous Bionx Implants Inc.) Osteo ACL Screw is stantially equivalent to the cleared predicate devices. The applied modifications do not raise any new concerns of safety and efficacy of the implant.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 7 2004

Ms. Tuija Annala
Director, Quality and Regulatory Affairs
Linvatec Biomaterials Ltd.
P.O. Box 3
Hermiankatu 6-8 L
FIN 33721
Tampere, Finland

Re: K032894
Trade/Device Name: Osteo ACL Screw™
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: February 18, 2004
Received: February 23, 2004

Dear Ms. Annala:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

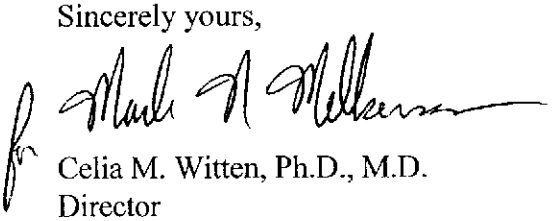
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(K) Number (if known): K032894

Device Name: Osteo ACL Screw

Indications for Use:

The Osteo ACL Screw™ is intended for use in interference fixation of bone-patellar tendon – bone and soft tissue grafts in anterior and posterior cruciate ligament reconstructions.

The Osteo ACL Screw™ is not intended for use in and is contraindicated for 1) insufficient quality and quantity of bone for attachment of graft, 2) Blood supply limitation and/or previous infections, which could retard healing, 3) Foreign body sensitivity to the implant material. Where the material is suspected a test should be made prior to implantation to rule out sensitivity, 4) Patients with active sepsis or infection, 5) Conditions, which tend to limit the patient's ability or willingness to restrict activities or follow directions during the healing and rehabilitation period, 6) ACL repairs, which would not be appropriate for fixation with metallic screws.

(Please do not write below this line – continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Yes OR Over-The-Counter Use No

(Per 21 CFR 801.109)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K032894